

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,419	06/07/2000	Tadashi Kohno	11127-002002	8455

26211 7590 11/21/2003

FISH & RICHARDSON P.C.  
45 ROCKEFELLER PLAZA, SUITE 2800  
NEW YORK, NY 10111

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
----------	--------------

1616

21

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/589,419

Applicant(s)

KOHNO ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2003 and 28 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,5,7-9 and 43-63 is/are pending in the application.
- 4a) Of the above claim(s) 43-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 5, and 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the following:
  - a. Paper No. 20, filed 8/28/03, wherein claim 5 was amended; and
  - b. the acceptable RCE and suspension request filed 6/27/03, Paper No. 18.

**Note:** Claims 3, 5, 7-9, and 43-63 are pending.

## **RESPONSE TO APPLICANT'S ARGUMENTS**

2. The Applicant's arguments filed 8/28/03 (Paper No. 20) to the rejection of claims 3, 5, and 7-9 made by the Examiner under 35 USC 103 and/or 101 has been fully considered and deemed non-persuasive for the reasons below.

### **103 Rejection**

The rejection of claims 3, 5, and 7-9 under 35 USC 103(a) as being unpatentable over Jindrich et al (Carbohydrate Research, 1995, Vol. 266, pages 75-80) in view of DeRosch et al (US Patent No. 5,300,280) is MAINTAINED for reasons of record in the office action mailed 1/24/03, Paper No. 13, and those found below.

Applicant asserts that Jindrich et al disclose a13C-methyl-cyclodextrin and does not teach or suggest labeling any form of modified cyclodextrins. Also, Applicant asserts that it would not be obvious to combine the references because the cyclodextrin, modified or unmodified, in DeRosch et al are not labeled themselves.

First, Applicant is reminded that the rejection was made in combination to two references. Hence, both references are not required to disclose every feature of the instant invention. In regards to DeRosch et al not disclosing labeled cyclodextrins, once

Art Unit: 1616

again, it is set forth that DeRosch was cited because it discloses the use of both modified and unmodified cyclodextrins. It illustrates that it is well known in the art to modify cyclodextrin or use the unmodified version. Thus, since the both references are directed to cyclodextrin compounds, a skilled practitioner in the art would be motivated to combine the documents.

Secondly, the claims read on 13C-labeled cyclodextrin OR a sugar molecule of an oligosaccharide/polysaccharide having at least one modifying group selected from the ones disclosed in Applicant independent claim 5. The claim does not exclude modified and unmodified cyclodextrin. Specifically, the claim as written does not require that the cyclodextrin have one of the modified groups of claim 5. If Applicant intends the cyclodextrin to have one of the modified groups as set forth in claim 5, it is respectfully suggested that the claims be amended to state so by, for example, including the phrase 'wherein cyclodextrin has at least one modifying group selected from...'. Thus, it would be clear that the 13C-methylated cyclodextrin of Jindrich et al is not encompassed in Applicant's invention. However, it should be noted that claim 9 which depends upon independent claim 5 is directed to 'the 13C-labeled oligosaccharide or polysaccharide or a salt thereof according to claim 5, which is 13C-cyclodextrin or  $\beta$ -galactosyl-13C-maltooligosaccharide'. Hence, indicating that it is not a requirement that the cyclodextrin contain any modifying group especially one selected from the ones disclosed in claim 5.

Art Unit: 1616

### WITHDRAWN CLAIMS

3. Claims 43-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

### ADDITIONAL REJECTION

#### 102 Rejection

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipate by Nunez et al (Biochemistry, 1980, Vol. 19, pages 489-495).

**Nunez et al** disclose the enzymatic synthesis and carbon-13 nuclear magnetic resonance conformation studies of disaccharides containing  $\beta$ -D-galactopyranosyl and  $\beta$ -D-[1-13C]galactopyranosyl residues (see entire document, especially, abstract; page 490, column 1, 'Materials and Method', first paragraph). Hence, both Applicant and Nunez et al disclose 13C-labeled oligosaccharides with a modifying group, galactosyl.

6. Claims 3, 5, 7, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipate by Heyes et al (Carbohydrate Research, 1992, Vol. 233, pages 1-14).

**Heyes et al** disclose the 13C-labeled MAS NMR spectra of cyclomaltohexose ( $\alpha$ -cyclodextrin) hexahydrate, cyclomaltoheptaose ( $\beta$ -cyclodextrin)


Art Unit: 1616

undecahydrate, and cyclomalto-octaose (gamma-cyclodextrin) octadecahydrate. [see entire document, especially, abstract; page 1, 'Introduction'; page 4, 'Results'; page 5, Figure 2; page 6, Table I]. Hence, both Applicant and Heyes et al disclose <sup>13</sup>C-labeled cyclodextrin compounds.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones  
Primary Examiner  
Art Unit 1616

November 14, 2003